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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,349	09/01/2004	Motohiro Ohta	09859/0201805-US0	1041

7278 7590 12/15/2006

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EXAMINER

HAGOPIAN, CASEY SHEA

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/506,349

Applicant(s)

OHTA ET AL.

Examiner

Casey Hagopian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-17,19-31,33-47,49-61 and 63-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-17,19-31,33-47,49-61 and 63-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/30/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Receipt is acknowledged of applicant's Amendment/Remarks filed 5/19/2006.

MAINTAINED REJECTIONS

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3-7, 9-10, 14, 15, 31, 33-37, 39-40, 45, 47, 49-53, 55-56, 61, 63-67, 69-70 and 75 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshinari et al. (US 2001/0001106 A1). Yoshinari discloses a composition that may be in the form of a tablet comprising D-mannitol and other various ingredients including pharmacologically active components such as pravastatin sodium, sweeteners, disintegrators such as low-substituted hydroxypropylmethylcellulose, carboxymethylcellulose, crospovidone and croscarmellose sodium, glidants such as light anhydrous silicic acid, synthetic aluminum silicate, silicon dioxide, calcium silicate, and magnesium silicate aluminate, and lubricants such as magnesium stearate, calcium stearate, stearic acid, and talc (abstract; paragraphs 0050, 0064-0065). Yoshinari also discloses D-mannitol having a specific surface area of not less than about 1 m²/g and exemplifies D-mannitol having specific surface areas of 0.7 m²/g and 0.5 m²/g (paragraph 0018, example 1). Yoshinari further discloses that the D-mannitol granules have an average diameter of about 0.05 to about 5.0 mm (i.e. about 50 to about 5,000

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microns). Yoshinari also exemplifies the claimed hardness of 20N or higher in figures 1, 5, 6, and 8 and crospovidone (e.g. disintegrant) in the amount of about 1.4% (example 6). Yoshinari further discloses methods of making the invention comprising the steps of granulating and compressing (examples). It should be noted that Yoshinari teaches that granulates comprising an entire formulation are subjected to compression (example 6), in other words, the granules of Yoshinari comprise all ingredients prior to compression. Yoshinari is silent to the particular limitation concerning solubility, however the disclosure of the specific compound pravastatin sodium inherently fulfills the claimed limitation, "wherein the solubility of the water-soluble pharmacologically active ingredient in water is 1 mg/ml or more" as it is stated on page 23 of the instant specification as well as on Cosmobio.com that pravastatin sodium has a solubility of about 100 mg/ml in water. Thus, the disclosures of Yoshinari render the instant claims anticipated.

4. Claims 1, 3, 7-11, 13-19, 23-27, 29-33, 37-41, 43-49, 53-57, 59-63, 67-71, and 73-76 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohta et al. (US 2001/0014340 A1). Ohta discloses a rapidly disintegrating tablet comprising various ingredients including D-mannitol, an active ingredient, light anhydrous silicic acid, a disintegrant such as crospovidone, croscarmellose sodium, and low substituted hydroxypropylcellulose, a lubricant such as magnesium stearate, stearic acid, stearyl alcohol, sucrose fatty acid ester and talc, a sweetening agent, a flavoring agent, and a coloring agent (pages 1-2; example 3). In particular, Ohta discloses that magnesium stearate is coated on a metal mold and dies of a hydraulic press exemplifying that the lubricant is contained on the outer surface of the tablet (example 3). Ohta also

discloses disintegration times of less than 30 seconds and hardness properties comparable to the claimed 20N or higher (table 1) as well as weight percentages of the active ingredient and light anhydrous silicic acid being 0.01-30% and 0.01-1%, respectively (paragraphs 0046 and 0049). The disclosure of these weight percentages fulfills the claimed ratio of pharmacologically active ingredient to adsorbent as being from 1:10 to 10:1. Ohta discloses weight percentages of D-mannitol being about 60-95% and the disintegrant being about 1-10% (paragraphs 0045 and 0047). Ohta further discloses methods of making the invention including the steps of granulation and compression (paragraph 0044). Thus, the disclosures of Ohta render the instant claims anticipated.

Response to Arguments

5. Claims 2, 18, 32, 48 and 62 have been cancelled in the amendment dated 5/19/2006, rendering any rejections associated with said claims moot.
6. Applicant's arguments, see page 14, filed 5/19/2006, with respect to the claim rejections under 35 USC 112 have been fully considered and are persuasive. The rejection of claims 12-14, 28-30, 42-44, 58-60 and 72-74 under 35 USC 112 has been withdrawn. However, upon further consideration the examiner has rejected said claims on new grounds (see *New Rejections* section of the rejection).
7. Applicant's arguments filed 5/19/2006 in regards to Yoshinari have been fully considered and they are persuasive in-part. Independent claim 17 and its depending claims have been amended to include new method steps in a particular order. The 102 rejection of claims 17-23 and 25-26 in view of Yoshinari has been withdrawn. However,

upon further consideration the examiner has rejected said claims under 35 USC 103 (see *New Rejections* section of the rejection). As for the remaining claims, the examiner finds applicant's arguments unpersuasive and has maintained the rejection under 35 USC 102. Applicant argues that Yoshinari does not teach fine granules comprising an active ingredient and an adsorbent selected from the group consisting of calcium silicate, light anhydrous silicic acid, synthetic aluminum silicate, silicon dioxide, and magnesium metasilicate aluminate. As discussed above, Yoshinari teaches said ingredients and granulation, specifically, granulates comprising a formulation that are then subjected to compression to form the final product. It is the position of the examiner that said granulates will include said ingredients and due to the "comprising" language used in the claims, other ingredients are able to be present. Thus, for these reasons the examiner respectfully disagrees with applicant's position.

8. Applicant's arguments filed 5/19/2006 in regards to Ohta have been fully considered and they are persuasive in-part. Independent claim 17 and its depending claims have been amended to include new method steps in a particular order. The 102 rejection of claims 17, 19-23, 25 and 26 in view of Yoshinari has been withdrawn. However, upon further consideration the examiner has rejected said claims under 35 USC 103 (see *New Rejections* section of the rejection). As for the remaining claims, the examiner finds applicant's arguments unpersuasive for the same reasons as discussed in the previous paragraph 7 of the Office Action and has maintained the rejection under 35 USC 102.

NEW REJECTIONS

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.** There is no teaching that the claimed disintegrator *comprises* at least one member selected from the group consisting of crospovidone, low-substituted hydroxypropylcellulose, croscarmellose sodium and carboxymethylcellulose; the subject matter is not properly described as filed.

Applicant's specification teaches that the disintegrator is at least one member selected from said group (see pages 9-10 and 26), however there is no teaching that the disintegrator may include other ingredients as the specific limitation "comprising" allows. Applicant is invited to identify the portion of the specification that teaches said limitation, as the examiner has not been able to locate the applicable disclosure. The claims within this rejection are examined as written by the applicant; at this time new matter must be considered as part of the claimed subject matter.

11. Claims 12-14, 28-30, 40-44, 58-60 and 72-74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a

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way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.** There is no teaching that the fine granules, D-mannitol and disintegrator are present in the amounts/percentages claimed. It is unclear what is the reference point, that is, is the claimed percentage of fine granules in terms of the entire composition? Applicant is invited to identify the portion of the specification that teaches said limitations, as the examiner has not been able to locate the applicable disclosure. The claims within this rejection are examined as written by the applicant; at this time new matter must be considered as part of the claimed subject matter.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

14. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely

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exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 3 recites the broad recitation "the disintegrator comprises", and the claim also recites "at least one member selected from the group consisting of..." which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 17, 19-23, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshinari et al. (US 2001/0001106 A1). Yoshinari teaches the elements discussed above in paragraph 3 of the rejection. Yoshinari is silent to the particular step of mixing fine granules comprising an active agent and an adsorbent (selected from the claimed group) and D-mannitol and a disintegrator. It would have been obvious to one of ordinary skill in the art to modify the method steps of Yoshinari because "selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results" (MPEP 2144.04). As such a practitioner would reasonably expect a rapidly disintegrable tablet comprising the aforementioned ingredients. Thus, in Yoshinari it would have been obvious to one of ordinary skill in the art at the time the invention was made to alter the order of the method steps.

19. Claims 17, 19, 23-27, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohta et al. (US 2001/0014340 A1). Ohta teaches the elements discussed above in paragraph 4 of the rejection. Ohta is silent to the particular step of mixing fine granules comprising an active agent and an adsorbent (selected from the claimed group) and D-mannitol and a disintegrator. It would have been obvious to one of ordinary skill in the art to modify the method steps of Ohta because "selection of any order of performing process steps is prima facie obvious in the absence of new or

unexpected results" (MPEP 2144.04). As such a practitioner would reasonably expect a rapidly disintegrable tablet comprising the aforementioned ingredients. Thus, in Ohta it would have been obvious to one of ordinary skill in the art at the time the invention was made to alter the order of the method steps.

Conclusion

20. All claims have been rejected; no claims are allowed.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-

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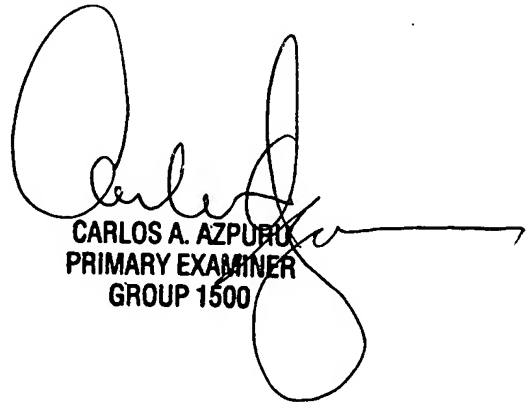
6097. The examiner can normally be reached on Tuesday through Friday from 8:00 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Casey Hagopian
Examiner
Art Unit 1615



CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500